

**REMARKS**

Claims 1-25 are pending in this application. Claims 19-25 have been newly added. Claims 1-10 and 12-18 have been amended.

Claims 1-10 and 12-18 have been amended. Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claims. Applicants reserve the right to reassert the full scope of any claim amended herein later in prosecution and/or in a continuing application.

Claims 19-25 have been newly added. Support for newly added claims 19-25 can be found throughout the specification and claims as originally filed. No new matter has been added.

Claims 1 and 13 have been amended to recite, in part, "...wherein the weight ratio of (i):(iii) is 5:4 and the weight ratio of (ii):(iii) is 1:4, the ternary system forming spontaneously a single phase stable, non-viscous...." Support for amended claims 1 and 13 can be found throughout the specification and claims as originally filed. For example, please see the specification at page 8, lines 6-12 (ratios) and page 2, line 12 (single phase).

Claims 1-10 and 12-18 have been amended to place them in proper US format. No new matter has been added.

Claims 19-25 have been newly added. Support for newly added claims 19-25 can be found throughout the specification and claims as originally filed. No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

- I. At page 2 of the Official Action, the specification has been objected to because the Brief Description of the Drawings should refer to the individual figures individually or collectively and reference thereto should correspond between the figure labels and the reference in the specification.***

The Brief Description of the Drawings has been amended to properly refer to the individual figures and reference thereto corresponds between the figure labels and the reference in the specification. Accordingly, the Examiner is respectfully requested to withdraw this objection.

- II. At page 2 of the Official Action, claims 1-6, 8-9, 11 and 13-18 have been rejected under 35 USC § 102(b) as being anticipated by Lynch et al.***

The Examiner asserts that Lynch et al. teaches each and every element of each of rejected claims 1-6, 8-9, 11 and 13-18.

In view of the following, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Independent claim 1 is directed to "A ternary system, comprising: (i) 40 to 65% water; (ii) 6 to 22% alcohol or a ketone; and (iii) 25 to 60% a fatty acid or an ester thereof, wherein the weight ratio of (i):(iii) is 5:4 and the weight ratio of (ii):(iii) is 1:4, the ternary

system forming spontaneously a single phase stable, non-viscous and clear nanosized structures having cubic-like nanosized symmetry." Claims 2-10, 19 and 20 each depend, directly or indirectly, from independent claim 1.

Independent claim 11 is directed to "A ternary system comprising 45 to 55% water, 30 to 45% glycerol monooleate and 6 to 15% C<sub>1</sub>-C<sub>4</sub> alcohol."

Independent claim 13 is directed to "A stable ternary system, comprising: (i) 40 to 65% water; (ii) 6 to 22% alcohol or ketone; and (iii) 25 to 60% fatty acid or an ester thereof, wherein the weight ratio of (i):(iii) is 5:4 and the weight ratio of (ii):(iii) is 1:4, the ternary system forming spontaneously a single phase stable, non-viscous and clear nanosized structures having cubic-like nanosized symmetry for use in solubilizing hydrophilic or hydrophobic substances in aqueous phase." Claims 14-18 and 21-24 each depend, directly or indirectly, from independent claim 13.

Lynch et al. do not describe the formation of a stable, non-viscous and clear nanosized structure having cubic-like nanosized symmetry, as recited in present claim 1.

In addition, the amendment to claim 1 clarifies and pin-points the technical feature which further distinguishes the system of the presently claimed subject matter from systems of the art. Claim 1 now recites the system which produces the unique Q<sub>L</sub> phase (Sample E) described in the specification. Lynch et al. do not disclose a single phase cubic ternary system. On the contrary, according to Lynch et al. ***at least one other phase is present together with the cubic phase.***

A careful analysis of Lynch et al. reveals that the publication is mainly directed to two types of solutions: (I) to cubic phase precursors, and (II) to cubic liquid crystalline forms (bulk as gel, dispersed). Both solutions are clearly and unambiguously different from the

system of claim 1:

In this regard, Applicant's submit that the cubic phase precursor is a completely irrelevant system. The cubic phase according to Lynch et al., in any of its forms, is formed from a precursor "*upon action by a stimulus*" (paragraph 0032) and also as described in paragraph 0102. Paragraph 0104 describes direct formation of the cubic phase by mixing directly the three components (*vide infra*). The last sentence in paragraph 004 clearly states that "*The precursor **must not** form a cubic phase gel*" (emphasis added). Claims 1-5 are directed to the precursor and are in accordance with the wordings of paragraph 0044. Claim 1 of Lynch et al. recites "*with the proviso that a, b and c **do not fall within a cubic liquid crystalline phase region** on a diagram representing phase behavior of ingredients (A), (B) and (C.)*" (emphasis added) Claim 2 further discloses that the relative concentrations of a, b and c, and indeed c (representing the concentration of the solvent, e.g. water), may be 0.

Additionally, in the liquid crystalline forms (bulk as gel, dispersed) of Lynch et al., a single phase, as claimed in presently amended claim 1, is **not** formed. Paragraph 0082 describes that the amounts of (A), (B) and (C) are different than those of the precursor and states:

*The amount of each ingredient must be such that the combined ingredients will form a cubic liquid crystalline phase **in combination with one or more other phases**. Any combination of the amounts of the ingredients that fall within the cubic liquid crystalline region in the phase diagram will be suitable for this invention. For example, referring to FIG. 1 again the amounts of water **109**, ethanol **103**, and monoolein **106** must be such that they fall in one of the cubic phase regions **115, 118** in the phase diagram.* (emphasis added)

This is reiterated in paragraph 0088:

*...and with the proviso that a, b, and c fall within a region representing cubic liquid crystalline phase **in combination with at least one other phase** on the phase diagram representing phase behavior of ingredients (A), (B), and (C), with the proviso that the dispersion has the form cubic liquid crystalline gel particles dispersed in the other phase. (Referring again to FIG 1, dispersions according to this invention fall within the region representing cubic liquid crystalline phase **in combination with another phase** 127 on the phase diagram 100). (Emphasis added)*

Table E1 (paragraph 0140) of Lynch et al. gives experimental results where it is apparent that ***no "single cubic liquid crystalline phase is formed."*** Where a cubic liquid crystalline phase forms, one always obtains ***a mixture of the cubic liquid crystalline phase with another phase*** in accordance with the description given in paragraphs [0082] and [0088].

In other words, the cubic liquid crystalline phase described by Lynch et al. is a ***mixture*** comprising cubic liquid crystalline phase ***together with another phase***. It is not directed to a single phase cubic system as presently claimed. Accordingly, Lynch et al. do not teach each and every element of the presently claimed subject matter as required for anticipation under 35 USC § 102.

The presently claimed subject matter is further inventive over Lynch et al. because it selects the appropriate boundaries for obtaining a pure single cubic phase and its use as a drug delivery system. The advantage of having one single cubic phase as opposed to a mixture of a cubic phase with another phase, is four-fold:

(1) The fact is that a Lamellar phase has a much lower solubilization capacity in comparison to a cubic phase and thus the total solubilization capacity of any mixture in accordance with invention of Lynch et al. will be significantly lower than that of the pure

cubic phase in accordance with the presently claimed subject matter. This is true for both water-soluble and oil-soluble bioactive materials.

(2) A mixture of two or more phases is difficult to control. Therefore, the variability in the content of the mixed cubic phases present in the system of Lynch et al. is high, i.e., one obtains uncontrolled ratios of Lamellar/cubic,  $L\alpha$ /cubic phases, whereas obtaining the pure cubic phase of the presently claimed subject matter is a controlled process yielding a single pure cubic phase.

(3) The bioavailability (downloading of the active material from its carrier- cubic or cubic/Lamellar- to the body) from Lamellar, hexagonal,  $L\alpha$  phases is **lower** than from the one obtained from a single pure cubic phase.

(4) The fact that the system according to the present invention is liquid and pourable with almost Newtonian-like properties helps to employ the system as such in topical applications. This is opposed to the more viscous or glassier mesophase-like systems disclosed by Lynch et al. that have visco-elastic properties which make their direct applications onto a skin of a subject more cumbersome.

In view of the foregoing, it is submitted that Lynch et al. do not teach each and every element of present claims 1-6, 8-9, 11 and 13-18 as required for anticipation under 35 USC § 102. Thus, it is submitted that claims 1-6, 8-9, 11 and 13-18 are novel in view of Lynch et al.

**III. At page 4 of the Official Action, claims 7 and 12 have been rejected under 35 USC § 103(a) as being unpatentable over Lynch et al. in view of Vatter et al.**

The Examiner asserts that Lynch et al. differs from claims 7 and 12 in the use of a ketone rather than the alcohol. The Examiner states that it “would have been obvious to one of ordinary skilled in the art at the time of applicants’ invention to employ flavor oils having ketones as an active ingredient in the compositions of Lynch et al. for part of or all of the part of (A), the hydrotrope.”

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time

the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

Lynch et al. is discussed in detail above and the discussion is incorporated herein. As discussed, Lynch et al. do not teach or suggest a single phase cubic system.

Vatter et al. is directed to cosmetic compositions where an association structure can be cubic liquid crystals.

Vatter et al. do not cure the deficiencies of Lynch et al. because Vatter et al. also do not teach or suggest a single phase cubic system as presently claimed. Please see the discussions regarding Lynch et al. set forth above and incorporated herein.

In view of the foregoing, it is submitted that nothing in Lynch et al. and Vatter et al., taken alone or together, render the presently claimed subject matter obvious within the meaning of 35 USC §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**IV. At page 5 of the Official Action, claim 10 has been rejected under 35 USC §**

**103(a) as being unpatentable over Lynch et al. in view of Spicer et al.**

The Examiner asserts that Lynch et al. differs from claim 10 in the use of a ketone rather than the alcohol. The Examiner states that "...it would have been obvious to one of ordinary skill in the art at the time of applicants' invention to employ encapsulating materials in the compositions of Lynch et al. for the advantages taught in the Spicer et al. reference."

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time

the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

Lynch et al. is discussed in detail above and the discussion is incorporated herein. As discussed, Lynch et al. do not teach or suggest a single phase cubic system.

Spicer et al. is directed to cubic liquid crystalline compositions and methods for their preparation. More specifically, Spicer et al. describes a dry powder cubic gel precursor comprising an encapsulating compound, an amphiphile capable of forming a cubic liquid crystalline phase, and optionally a solvent.

Spicer et al. do not cure the deficiencies of Lynch et al. because Spicer et al. also do not teach or suggest a single phase cubic system as presently claimed. Please see the discussions regarding Lynch et al. set forth above and incorporated herein.

In view of the foregoing, it is submitted that nothing in Lynch et al. and Spicer et al., taken alone or together, render the presently claimed subject matter obvious within the meaning of 35 USC §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

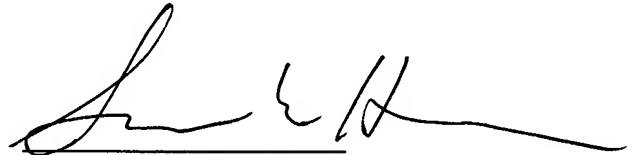
**CONCLUSION**

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

**THE NATH LAW GROUP**

A handwritten signature in black ink, appearing to read 'Susanne M. Hopkins', written over a horizontal line.

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